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TITLE: Chemotherapy-Induced Alopecia and Symptom Distress in Younger and Older Women with Breast Cancer: Intergroup Differences and Impact on Functional Status

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# Abstract

**Purpose:** The purpose of this training grant is to facilitate development of breast cancer (BC) clinical research skills, particularly related to issues relevant to older women.

**Scope:** The research training program encompasses didactic coursework, secondary analysis, and dissertation research within the doctoral program at the School of Nursing, and intensive mentored clinical research training at the Abramson Cancer Center, both at the University of Pennsylvania.

**Major Findings:** A secondary analysis was conducted to longitudinally compare symptom distress and functional status in older (n=26) versus younger (n=163) women receiving 4-8 cycles of adjuvant BC chemotherapy. Compared to younger women, older women trended towards greater declines in functional status from baseline to cycle 4. Older women had significantly lower symptom distress during the first week following chemotherapy than did younger women, but no difference were seen at any other timepoint. Age, race, baseline functional status, and coincident change in symptom distress together explained 55.9% of the variance in functional status change between cycle 1 and 4 (p,0.0001).

**Progress:** Secondary analysis is complete with preliminary findings presented in poster format and final results planned for oral presentation in 11/05. Twelve of 13 required courses for the Ph.D. have been completed, the dissertation research proposal defended, and dissertation data collection will begin 4<sup>th</sup> quarter 2005.

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## Introduction and Body

In the second year of funding for this training grant, I have made significant further progress towards achieving my stated objectives outlined in my approved Statement of Work, with several tasks fully completed at this time. A no-cost extension will allow completion of the remaining tasks in the third year of funding.

### 1) *Task 1: Participate in educational activities which extend over the entire award period.*

I have participated continuously in all of the outlined activities at the University of Pennsylvania (Penn), including ongoing participation in and scholarly presentations at the School of Nursing's Geroscholars seminar held by the Hartford Center for Excellence in Geriatric Nursing Education, the Rena Rowan Breast Cancer Research & Clinical Trials meeting, as well as Grand Rounds, journal clubs, and pertinent Clinical Research Unit meetings of the Abramson Cancer Center.

I have completed 12 of 13 courses required for the PhD degree, and the final course will be completed by December 2005 (See Appendix A).

### 2) *Task 2: Engage in a structured research residency pertaining to the conduct of clinical cancer research.*

I have completed the 24 month requirement to attend selected meetings of the Institutional Review Board at Penn with my mentor Lynn Schuchter, MD, as well as selected additional research meetings (see year 1 Annual Report).

I have completed my mentored participation in data collection, management, and analysis for the Abramson Cancer Center trial UPCC 03101: The Pattern, Correlates, and Functional Impact of Anemia, Fatigue, and Nausea and Vomiting in an Adjuvant Treatment Setting for Early Stage Breast Cancer, and this study is now closed. This study was separately funded by Merck & Co., Inc., and Ortho Biotech, Incorporated. Please see year 1 annual report for full description of this research training experience and associated reportable outcomes, as well as documentation of my fulfillment of the PhD Research Residency requirement.

### *Task 3: Participate in subject recruitment, targeting older (>60) women with breast cancer to ensure adequate representation in UPCC 03101.*

Complete. I have completed oversight of subject recruitment and enrollment for UPCC 03101.

- 94 subjects enrolled during years 1 and 2 of funding
- 210 subjects in total accrued since March 2002, meeting target enrollment.
- 27 subjects are 60 years and older. Mean age = 48.6 years, range = 25 to 77 years. The low percentage (12.8%) of older women in this study reflects the relatively low percentage of older women receiving chemotherapy for adjuvant breast cancer treatment.

Older women will be a subpopulation specifically recruited to the dissertation research study, which targets breast cancer survivors diagnosed with Stage 0-III breast cancer. Since receipt of chemotherapy is not an inclusion criteria for this study, a larger sample of potentially eligible older women will exist.

### *Task 4: Data Analysis, UPCC 03101.*

Complete. During this second funding year I presented an additional poster at an international oncology meeting (MASCC) relevant to the primary aims of UPCC 03101 (See "Reportable Outcomes"), in addition to the 2 poster presentations in year one. Secondary analysis related to

age differences in symptom experience and functional status is complete. I presented preliminary findings in poster format at the Era of Hope conference, and will present final results as a paper at the annual meeting of the Gerontologic Society of America (GSA). (See "Reportable Outcomes" and Appendix B).

*Task 5: Develop the design and methods of the dissertation research study.*

Complete. Dissertation research proposal defended 6/8/05, titled "Patterns and Determinants of Physical Activity and Exercise in Older versus Younger Female Breast Cancer Survivors". Achievement of this task was delayed due to further refinement of dissertation study aims and measures in conjunction with completion of required PhD coursework. (See Appendix C for dissertation proposal abstract & Appendix D for documentation of proposal defense).

*Task 6: Data Collection for the Dissertation Research Study*

- Initiation of data collection for dissertation research study pending local Institutional Review Board (IRB) approval and subsequent Department of Defense Human Subjects Review Board (HSRB) approval.

*Task 7: Data Analysis, dissertation research study.*

- Data analysis for the dissertation research study anticipated to begin in January 2006.  
- Preliminary exam questions have been finalized, committee formed, and defense anticipated November 2005.

*Task 8: Prepare and submit manuscripts for publication*

- See "Reportable Outcomes". In addition, following my presentation of secondary analysis results from UPCC 03101 at the GSA annual meeting in 11/05, I will be working this paper into a manuscript for publication.

**Key Research Accomplishments (7/1/04– 6/30/05)**

- 1) Completed enrollment and data collection for UPCC 03101, "The Pattern, Correlates, and Functional Impact of Anemia, Fatigue, and Nausea and Vomiting in an Adjuvant Treatment Setting for Early Stage Breast Cancer", funded separately as described above in Task 2.
- 2) Completed both primary and secondary data analysis for UPCC 03101.
  - a. Presented findings relevant to UPCC 03101 primary aims at the 17<sup>th</sup> Annual Multinational Association of Supportive Care in Cancer (MASCC) International Symposium on Supportive Care in Cancer.
  - b. Presented preliminary secondary analysis results as a poster at the Department of Defense 2005 Era of Hope conference, and will present final results as a paper within the Presidential Symposium at the annual meeting of the Gerontologic Society of America (GSA), November 2005.
- 3) Presented results of the PhD Qualifying Exam as a paper at the 57th Annual Scientific Meeting of the Gerontological Society of America (November 22, 2005).
- 4) Defended the dissertation research proposal on 6/8/05; study initiation pending IRB and HSRB approval.

## **Reportable Outcomes:**

### Publications:

#### *Peer reviewed articles*

Stricker, C. T., Drake, D. A., Hoyer, K. A., & Mock, V. (2004). Evidence-Based Practice for Fatigue Management in Adults with Cancer: Exercise as an Intervention. *Oncology Nursing Forum* 31(5), 963-976.

Jacobs, L. A. & Stricker, C. T. (2005). Essential components of a patient-focused practice model for cancer survivors. *American Journal of Nursing*, in press.

#### *Peer-reviewed Abstracts/Presented Papers*

Stricker, C. T. (2004). *Examination of exercise interventions for older adults: population, function, and health.* The Gerontologist 44(Sp. Iss. 1), 507-508. (Paper presented at the Gerontologic Society of America's 57<sup>th</sup> Annual Scientific Meeting Program, Washington, D.C. November 22). (Abstract included in Year 1 Annual Report)

Stricker, C. & Sullivan, J. (2005). Implementation of an evidence based oral care guideline changes practice at a NCI-designated cancer center. *Oncology Nursing Forum* 32(1), 173. (Paper presented at the 8th National Conference on Cancer Nursing Research, Ft. Lauderdale, FL. February 5).

Stricker, C. T. (2005). Patterns and predictors of functional status and symptom distress in older versus younger women undergoing adjuvant breast cancer chemotherapy. *Proceedings of the 2005 Era of Hope Department of Defense Breast Cancer Research Program Meeting*, p. 147. (Poster; Philadelphia, PA. June 9).

Stricker, C. T. & Velders, L. (2005). Predictors of chemotherapy-induced nausea and vomiting in women with early stage breast cancer. *Supportive Care in Cancer* 13(6). (Poster presented at the MASCC 17<sup>th</sup> International Symposium on Supportive Care in Cancer; Geneva, Switz.; July 1).

### Presentations:

#### *Professional*

- 2005 "Exercise for Individuals with Cancer: What is the Evidence?"  
- Instructional Session, 'Exercise Programs for Cancer Patients'  
Oncology Nursing Society 30<sup>th</sup> Annual Congress, Orlando, FL; April 30.
- 2005 "The Role of the Advanced Practice Nurse in Cancer Survivorship Programs"  
- Symposium, 'Management of the High-risk Patient with Breast Cancer'  
29th Annual Symposium of the American Society of Breast Disease, Las Vegas; Apr 21.

#### *Public/Lay*

- 2005 "Managing Side Effects of Breast Cancer Treatment"  
Living Beyond Breast Cancer/Young Survival Coalition Annual Young Survivors Conference, Philadelphia, PA; February 19.

Research opportunities:

1) Invited Co-Investigator on the study "Prospective Outcomes in Survivors of Solid Tumors (POST) - Breast Cancer Protocol," a longitudinal study of quality of life and late effects of treatment in breast cancer survivors. POST is conducted within the Abramson Cancer Center of the University of Pennsylvania with funding from the Lance Armstrong Foundation.

Funding:

**Stricker, C.T. (\$15,000)**

American Cancer Society, Doctoral Scholarship in Cancer Nursing

8/01/05-7/31/06

"Physical Activity Determinants and Behavior in Older Breast Cancer Survivors"

**Conclusions:**

Significant additional progress has been made in year two towards achieving the objectives of the Clinical Research Nurse Award training grant, with several tasks completed. Secondary analysis is complete with preliminary findings presented in poster format and final results planned for oral presentation in November 2005. Please see abstracts of these presentations included in Appendix B for a summary of findings. Twelve of 13 required courses for the PhD degree have been completed (See Appendix A), the dissertation research proposal successfully defended (Appendix C & D), and dissertation data collection will begin 4<sup>th</sup> quarter 2005.



**APPENDIX A:**  
**Doctoral Coursework**

Completed during the FY2005 funding period

- Epidemiology 542: Measurement of Health in Epidemiology
- Nursing 900: Functional Adaptation to Chronic Illness in Older Adults (Directed Study)
- Nursing 900: Exercise Physiology & Physical Activity Measurement: Applications to Clinical Research in Older Adults with Cancer (Directed Study).
- Sociology 536: Quantitative Methods in Sociology II (Statistics II).

Completed during the FY2004 funding period

- Nursing 753: Evolving Nursing Science
- Nursing 813: Qualitative Paradigm Empirical Nursing Research
- Nursing 816: Health Status, Functional Status, & Quality of Life
- Nursing 800: Dissertation Seminar
- Public Health Studies 504: Behavioral and Social Sciences in Public Health

Completed prior to funding

- Nursing 750: Inquiry and Nursing
- Nursing 754: Quantitative Research Design and Methods
- Sociology 535: Quantitative Methods in Sociology (Statistics I)

In progress

- Nursing 840: Proseminar in Advanced Quantitative Designs and Methods for Nursing and Health Research

**APPENDIX B:**  
**Published Research Abstracts**

**Preliminary Secondary Analysis Results:**

Stricker, C. T. (2005). Patterns and predictors of functional status and symptom distress in older versus younger women undergoing adjuvant breast cancer chemotherapy. *Proceedings of the 2005 Era of Hope Department of Defense Breast Cancer Research Program Meeting*, p. 147. (Poster; Philadelphia, PA. June 9).

Women 65 and older constitute over 50% of new breast cancer cases in the United States, yet are significantly under-represented in clinical cancer research. The number of older women receiving adjuvant chemotherapy for early stage breast cancer is growing, yet little is known about how these women's unique experiences of symptom distress and functional status throughout chemotherapy compare to those of younger women. Recent studies of women receiving heterogeneous treatments have yielded conflicting results. Furthermore, predictors of symptom distress and functional status are not well understood in this population. The purpose of this study is to compare symptom distress and functional status in older versus younger women receiving adjuvant breast cancer chemotherapy, and to identify predictors of functional status changes in this population.

A secondary analysis was performed on a dataset from a longitudinal study examining relationships between symptom distress, anemia, and functional status in women during and following anthracycline-based adjuvant chemotherapy for early stage breast cancer. Symptom distress (Symptom Experience Scale) was measured at baseline before chemotherapy, on Day 1 of cycles 2 and 4, on Day 8 of cycles 1 and 4, and 6 weeks and 3 months following the completion of chemotherapy. Hemoglobin (g/dL) and functional status (Inventory of Functional Status-Cancer) were measured concurrently, except on Day 8. Baseline demographic and treatment variables included age, race, stage, type of surgery, and days since surgery. Change scores were calculated by subtracting the score for a variable at one timepoint from its corresponding score at an earlier timepoint.

Data from 159 women (mean age=49 years, range 25-77) were analyzed. Older women were defined as those 60 years or older (n=22), and younger women, less than 60 years (n=137). In each group, functional status and hemoglobin declined significantly from baseline to cycle 4, and returned to or above baseline by 3 months following chemotherapy. Symptom distress exhibited the reverse pattern. Compared to younger women, older women experienced significantly greater declines in functional status from baseline to cycle 4, despite lack of significant differences in functional status at any one timepoint. Conversely, while older women had significantly lower symptom distress than younger women at several timepoints, there were no significant differences in symptom distress change scores between older and younger women. Coincident change in symptom distress and hemoglobin, as well as age, explained 40.3% of the variance in change in functional status between cycle 1 and 4 ( $p<0.0001$ ), with change in symptom distress being the strongest predictor. No other demographic/treatment variables explained differences in functional status.

Older women represent the largest population of women with breast cancer in the United States, and are at risk for greater declines in functional status during adjuvant chemotherapy. Minimizing symptom distress and anemia may help to prevent functional status declines in these women.

**Final Secondary Analysis Results:**

Stricker, C. T. (2005). *Patterns and predictors of functional status and symptom distress in older versus younger women undergoing adjuvant breast cancer chemotherapy*. (Paper to be presented as part of Presidential Symposium 'Critical Issues in Interdisciplinary Gero-Oncology Care' at the 58th Annual Meeting of the Gerontological Society of America; New Orleans, LA. November 19 and abstract to be published in *The Gerontologist*).

Women 65 and older constitute over 50% of new breast cancer cases in the United States, yet are significantly under-represented in clinical cancer research. The number of older women receiving adjuvant chemotherapy for early stage breast cancer is growing, yet little is known about how these women's unique experiences of symptom distress and functional status throughout chemotherapy compare to those of younger women. Recent studies of women receiving heterogeneous treatments have yielded conflicting results. Furthermore, predictors of symptom distress and functional status are not well understood in this population. The purpose of this study is to compare symptom distress and functional status in older versus younger women receiving adjuvant breast cancer chemotherapy, and to identify predictors of functional status changes in this population.

A secondary analysis was performed on a dataset from a longitudinal study examining relationships between symptom distress, anemia, and functional status in women during and following anthracycline-based adjuvant chemotherapy for early stage breast cancer. Symptom distress (Symptom Experience Scale) was measured at baseline before chemotherapy, on Day 1 of cycles 2 and 4, on Day 8 of cycle 1, and 3 months following the completion of chemotherapy. Hemoglobin (g/dL) and functional status (Inventory of Functional Status-Cancer) were measured concurrently, except on Day 8. Baseline demographic and treatment variables included age, marital status, race, stage, type of surgery, and days since surgery. Change scores were calculated by subtracting the score for a variable at one time point from its corresponding score at an earlier time point.

Data from 189 women (mean age=48.8 years, range 25-77) were analyzed. Older women were defined as those 60 years or older ( $n=26$ ), and younger women, less than 60 years ( $n=163$ ). In each group, functional status and hemoglobin declined significantly from baseline to cycle 4, and returned to or above baseline by 3 months following chemotherapy. Symptom distress exhibited the reverse pattern. Compared to younger women, older women experienced a trend towards greater decline in functional status from baseline to cycle 4, despite lack of significant differences in functional status at any one time point. Older women had significantly lower symptom distress and rises in symptom distress during the first week following chemotherapy than did younger women, but there were no significant differences in symptom distress at any other time point. Age, race, baseline functional status, and coincident change in symptom distress together explained 55.9% of the variance in change in functional status between cycle 1 and 4 ( $p<0.0001$ ). No other demographic/treatment variables explained differences in functional status.

Older women represent the largest population of women with breast cancer in the United States, and are at risk for greater declines in functional status during adjuvant chemotherapy. Minimizing symptom distress may help to prevent functional status declines in these women.

#### **UPCC 03101 Analysis of primary aims**

Stricker, C. T. & Velders, L. (2005). Predictors of chemotherapy-induced nausea and vomiting in women with early stage breast cancer. *Supportive Care in Cancer* 13(6). (Poster presented at the MASCC 17<sup>th</sup> International Symposium on Supportive Care in Cancer; Geneva, Switzerland, July 1).

Women receiving adjuvant chemotherapy for early-stage breast cancer experience significant chemotherapy-induced nausea and vomiting (CINV). Identification of risk factors is critical for effective and economical CINV prevention, yet few studies have specifically examined CINV risk factors in this population.

A sample of 100 women receiving Adriamycin and Cytosan (AC) for Stage I-III breast cancer were evaluated for the following baseline factors: age, weight, history/severity of pregnancy-related nausea/vomiting, alcohol use/quantity, current use of anxiolytics/antidepressants, history/severity of motion sickness, and patient CINV expectations. During the first AC cycle, subjects recorded in a 5-day diary the number of emetic episodes each day, daily severity of nausea on a visual analog scale (VAS), and medications taken for prevention/treatment of CINV. Acute CINV was defined as CINV in the first 24 hours following chemotherapy; delayed CINV was from 25-120 hours.

Data are available on 88 women (mean=48.7 years) who all received a minimum combination of a serotonin-receptor antagonist (5HT3-A) and dexamethasone as Day 1 antiemetic prophylaxis. For delayed CINV prophylaxis, the most common regimens were 5HT3-A alone (n=59, 68%) or 5HT3-A/dexamethasone (n=21, 24%). 19.2% of women experienced  $\geq 1$  acute emetic episodes, and 23.8% had delayed emesis. Nausea was more prevalent, with 50% reporting acute nausea (VAS>5), and 62.5%, 63.6%, 52.9%, and 42.2% reporting delayed nausea on Days 2-5, respectively. In univariate and multivariate linear regression, age and current anxiolytic/antidepressant use were statistically significant predictors of acute emesis, together explaining 11% of the variance ( $p=0.007$ ). For predicting delayed emesis, anxiolytic/antidepressant use was the only variable approaching significance ( $p=0.08$ ). Predictors for delayed nausea were analyzed daily (Days 2-5). In univariate analyses, increasing age and severity of acute nausea were statistically significant predictors. However, in multivariate analysis, acute nausea became the only significant predictor of delayed nausea, explaining 14.4 to 39.6% of the variance in delayed nausea on Days 2-5 ( $p<0.001$ ). CINV rates during adjuvant breast chemotherapy are most consistent with those seen during highly emetogenic chemotherapy, and risk factors can help target more effective CINV treatment.

**APPENDIX C**  
**Dissertation Proposal Abstract**

**Dissertation Proposal: FINAL**

**Patterns and Determinants of Physical Activity and Exercise in Older versus Younger Female  
Breast Cancer Survivors**

**Carrie Tompkins Stricker**

**June 27, 2005**

## Abstract

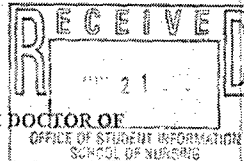
Over 200,000 women in the United States receive a diagnosis of breast cancer each year, and over half are 60 years of age or older. More than 80% of all women diagnosed with breast cancer will become long term survivors of their disease. These breast cancer survivors (BCS), and older women in particular, are at higher risk than the general population for a number of negative health outcomes, including cardiovascular disease, osteoporosis, and additional malignancies, as well as increased symptoms, functional impairment, and decreased quality of life. Fortunately, health behaviors such as physical activity (PA) have the potential to modify women's risk of developing these late effects. Unfortunately, the majority of breast cancer survivors do not engage in recommended levels of PA, and recent interventions have failed to improve PA participation in the majority of BCS. Older BCS appear at greatest risk for inadequate PA levels. A critical step towards effectively increasing PA in BCS is to identify and describe predictors of PA which can be targeted with interventions. Social cognitive theory (SCT) has consistently demonstrated high predictive power for understanding PA, positing that cognitive, environmental, and behavioral factors interact to determine PA. In preliminary studies, SCT constructs (self-efficacy [SE], outcome expectations [OE], and perceived barriers [PB]) are significant predictors of PA in women undergoing adjuvant breast cancer therapy. They have not, however, been specifically examined in BCS following treatment, nor in older BCS. Therefore, the fundamental goal of this study is to describe PA behavior and its modifiable determinants in order to guide future intervention aimed at increasing PA in BCS. The specific aims are to 1) describe and compare SCT constructs and their relationship to PA between older ( $\geq 60$  years) and younger ( $< 60$  years) female BCS. This cross-sectional study will take place within the Living Well After Cancer (LWAC) program at the Abramson Cancer Center of the University of Pennsylvania. BCS who are 1-2 years post-diagnosis will be recruited from LWAC's longitudinal breast cancer study. Instruments measuring PA and PA-specific SCT constructs will be administered and compared between age groups. These data will ultimately lead to the development of age-specific interventions aimed at improving PA behavior in both older and younger BCS.



**APPENDIX D**  
**Documentation of Dissertation Proposal Defense**

UNIVERSITY OF PENNSYLVANIA  
School of Nursing

REPORT OF PROPOSAL DEFENSE EXAMINATION FOR THE DOCTOR OF  
PHILOSOPHY DEGREE



The proposal defense of Carrie T. Stricker  
entitled Patterns + Determinants of PA Exercise in Older was  
held on 8th from 10.3-12 of June The decision of the Examining Committee is:  
PASS

- A. Both the proposal and oral explanation are satisfactory.
- B. Minor changes are recommended by the committee that are to be made to the satisfaction of the Chairperson.
- DEFER
- A. Minor changes in the proposal are required. Changes must be to the satisfaction of the committee.
- B. Major changes in the proposal are required. Changes must be to the satisfaction of the committee.
- FAIL
- Neither the oral performance nor the proposal are adequate.

Signatures of the Committee

<u>Kevin E. Skemp</u>	Chairperson
<u>Lorraine Tulmon</u>	Member
<u>Lynn Schuch</u>	Member
<u>Sally C. Volz</u>	Reader
<u>James H. Koppa</u>	Reader
<u>John A. ...</u>	Graduate Group Chair